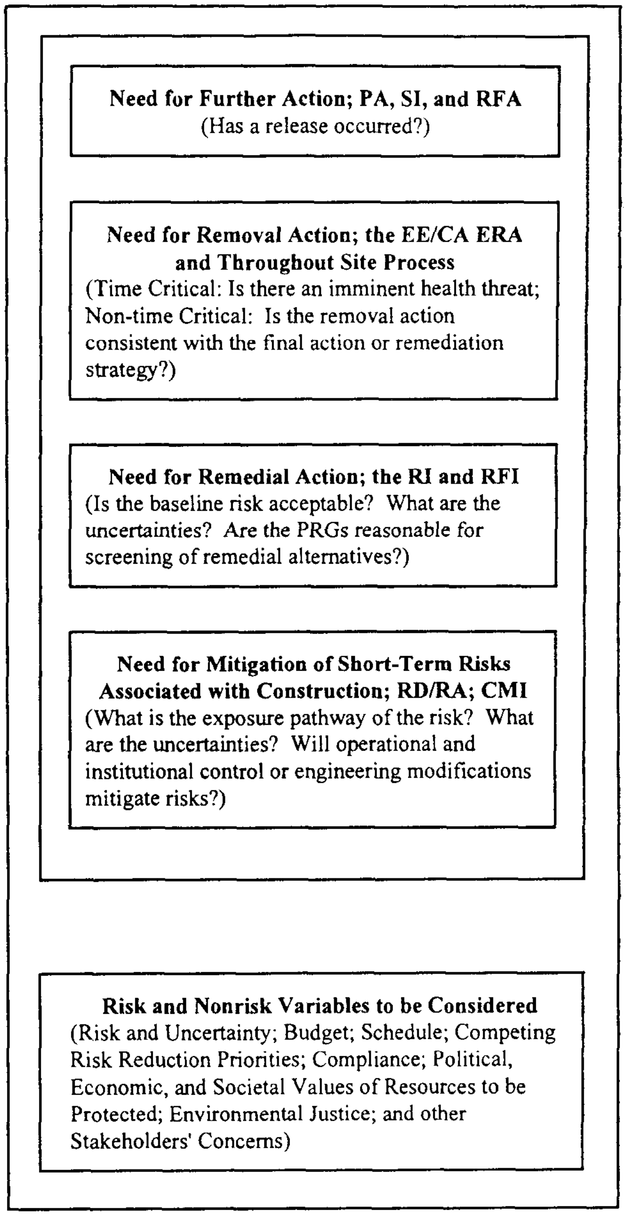
Chapter 9
Risk Management -- Information Needed for Decision-Making

9.1 Introduction

The National Academy of Sciences (NAS) defines risk management as "a process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision" (NRC 1983). NAS has identified four key components for managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC 1994). Risk characterization is considered the "bridge" or "interface" between risk assessment and risk management. EPA recommends that risk characterization should be clearly presented and separated from any risk management considerations. EPA (1995d) policy indicates that risk management options should be developed using risk input and should be based on consideration of all relevant factors, both scientific and nonscientific.

Consistent with NAS, USACE has developed the HTRW risk management decision-making (RMDM) process. This process identifies factors to consider when making decisions, developing and recommending options, and documenting of risk management decisions (Figures 9-1, 9-2). The process establishes a framework to manage risk on a site-specific basis. It emphasizes that risk management must consider the strengths, limitations, and uncertainties inherent in the risk assessment; the importance of public and other stakeholders' input; and other nonrisk factors. DoD has developed a similar concept to help prioritize installations according to environmental risks (see Section 1.3.1.1).

Risk and uncertainty are important factors to be considered in RMDM (EPA 1991d, 1995d). Other factors, including the customer's and stakeholders' concerns, cost, schedule, value of resources to be protected, political, and technical feasibility, are also to be considered before selecting the best option for a project decision. The consideration of risk is critical, since site actions are



Fibure 9-1. Inputs for risk management decision-making HTRW project decision diagram

What is the project decision for the project phase?
(Regulatory/Statutory Decision Statement)

What are the inputs/study elements into the decision?
(Comparison with health-based PRGs, screening risk assessment, baseline risk assessment, risk analysis of alternatives, development of remedial action objectives)

What are the anticipated options?
(Interim measures, removal actions, ARARs)

What are the risk and uncertainty?
(Reasonable maximum/high-end; average; population; and probabilistic risks)

What are other relevant nonrisk factors?
(Risk; Uncertainty; Budget; Schedule; Competing Risk Reduction Priorities; Compliance; Political, Economic, and Societal Values of Resources to be protected; Environmental Justice; and other Stakeholders' concerns)

What are the options?
(An array of potential options and their ramifications on the site decision)

What is the recommended option?
(and the rationale for the recommended option)

Decision by the Customer and
Document Rationale for Decision

Figures 9-2. HTRW risk management decision-making process flow diagram driven by statutes and regulations which explicitly require the "protection of human health and the environment"[1]

Therefore, selecting the proper risk tool and collecting data to assess environmental risk are primary responsibilities of the PM and the risk assessor.

The HTRW risk management decision-making process can be represented by the following equation, with many variables contributing to the final decision:

$$RM = f(X_1, X_2, X_3, X_4 \ldots X_N)$$

where

RM = risk management decision

f = function of

X_i = input variables (e.g., risk and uncertainty)

In addition to risk and uncertainty, there are many nonrisk variables influencing the risk management decision. The major ones are cost, schedule, value of resources to be protected, competing risk reduction priorities among sites managed by the customer, compliance/regulatory, political, economic. and technical feasibility. A relatively sensitive political and/or economic factor to be considered is "Environmental Justice or Equity." This phrase relates to the government's initiatives to clean up sites located in "poor and disadvantaged" areas.

The risk assessment, in conjunction with other important "nonrisk" decision criteria, provides information on the need for remedial or early actions. Therefore, a clear understanding of the risk assessment results and their uncertainties is essential. Informed risk management decision-making will lead to protection of human health and the environment; cost saving: meeting the agreed schedule: political harmony; better management of resources; and other social and economic benefits. The HTRW RMDM process is consistent with recent initiatives by various EPA officials: Habicht (EPA 1992g). Denit (EPA 1993i). Browner (EPA 1995a). DoD (1994a) and various proposed legislations by the 104th Congress (e.g., Dole-Johnston Bill (S-343) and HR 1022) suggest that the need for risk reduction be based on "real world" or realistic risk assessment, cost benefit analysis, and prioritization of environmental issues. The HTRW RMDM paradigm (Figure 9-3) presents an overview of this process.

Prior to gathering data and performing the ERA, the PM defines the site decision for the project phase, the required study elements (types of ERA or risk tools to be used), and the potential uncertainties associated with the outputs of the study element. Based on risk information and other considerations, the customer can select from an array of recommended risk management options. Options can include gathering additional data, recommending no further action, interim measures, or removal and/or remedial actions. To facilitate RMDM, the USACE PM should anticipate potential risk management options early in the project planning phase. Examples of the use of risk assessment in various project phases include:

- PA/SI or RFA: A screening risk assessment, an environmental mapping, and an exposure pathways analysis may be performed to determine the need for further investigations.

- RI or RFI (prior to FS and CMS): The. baseline ERA determines the need for the remedial action.

- FS or CMS: Results of the ERA are used to develop preliminary remedial goals (i.e., chemical concentrations which pose acceptable hazard or ecological effects).

- FS or CMS: Qualitative or quantitative risk assessments to compare and evaluate potential ecological impacts from the remedial alternatives. A qualitative or simple quantitative risk assessment (like those used in the baseline ERAs) may be conducted to screen alternatives for their potential short-term and residual risks.

- RD (prior to conducting RA and CMI): Detailed risk analysis may be performed to determine if protective measures should be taken to minimize the impact to health and the environment during remediation. For example, a toxicity assessment

[1] Examples of these. requirements are 40 CFR 300.430(e)(1) of the NCP for deciding if remedial action is needed for a CERCLA site; RCRA Sections 3004(u), 3004(v), 3008(h), 7003 and/or 3013 for requiring corrective actions at hazardous waste treatment, storage, and disposal facilities to protect human health/environment; and the risk-based determination for no-further action (40 CFR 264.514) and selection of remedy (40 CFR 264.525) under the proposed Subpart S RCRA corrective action rules.

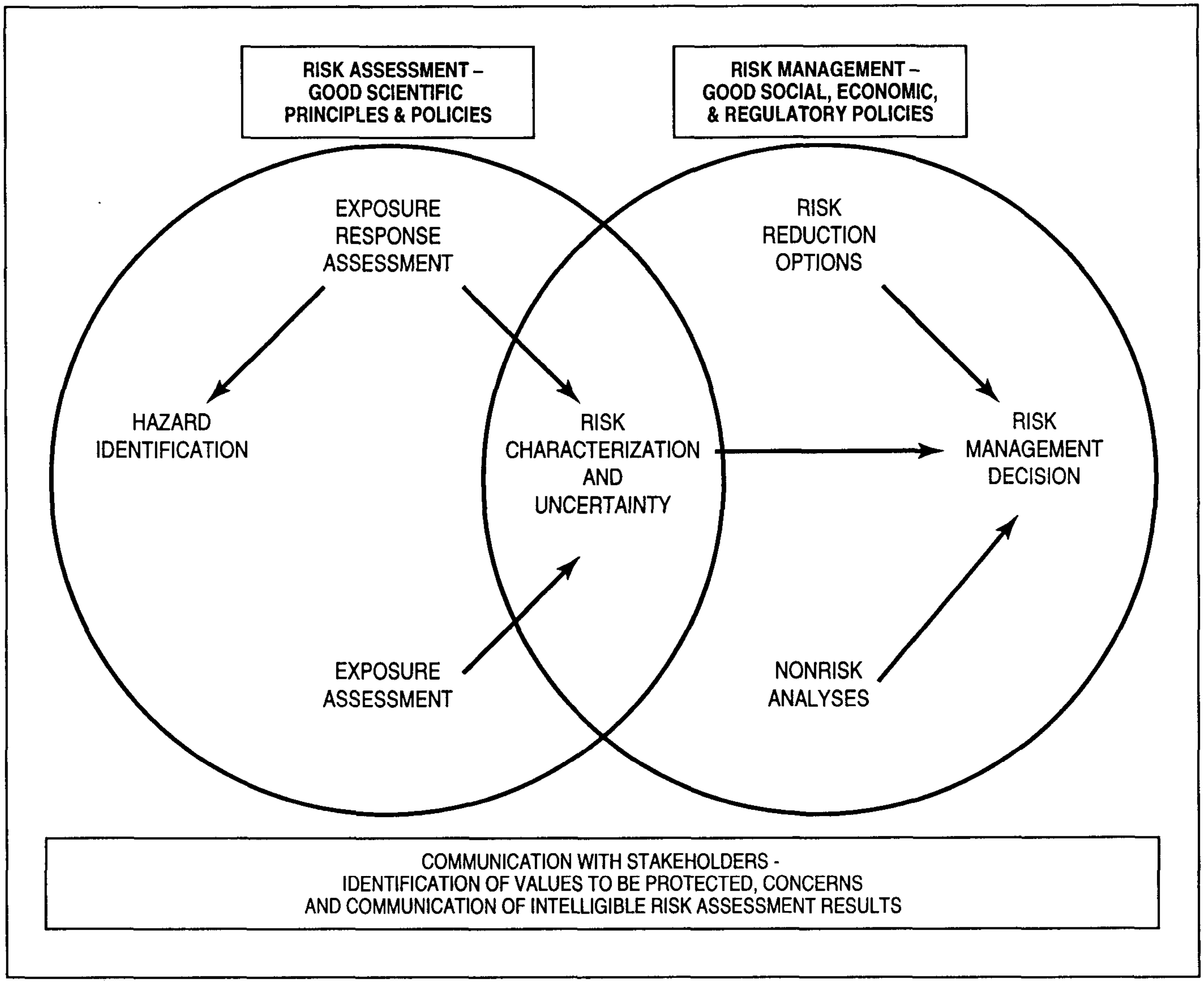


Figure 9-3. HTRW paradigm for risk management decision-making

may be conducted to evaluate the short-term acute, subchronic, and chronic ecotoxicities of potential releases from the remediation process. A hazard-response assessment should also be conducted to determine the design measures to reduce the impact of nonchemical stressors, e.g., habitat alteration and destruction, siltation, or other physical or chemical changes in the environment caused by construction of the remediation.

This chapter describes how the results of risk assessment procedures are to be used in risk management decision-making. The decisions include the need for further investigation, removal and remedial actions, selection of remedy, and provision of measures for designing removal or remedial actions that are protective of the environment (Figure 9-1). Information provided by the risk assessment is a key for selecting risk management options. Further, potential removal or remedial alternatives should be evaluated and compared according to their effectiveness to reduce site risks, and any associated short-term risks posed by implementation of the alternatives.[2]

It is important to recognize that risk managers often make difficult decisions with considerable uncertainties in both risk and nonrisk information. Therefore. a focused and balanced risk approach is recommended that recognizes the reasonable limits of uncertainty for the protection of human health and the environment as the primary consideration, along with the considerations for nonrisk issues. The risk manager should clearly communicate the decision and the associated assumptions and document the basis for the decision. This chapter is organized to present the following information:

Section 9-2 describes how risk information can be used to support project decisions at various project phases (e.g., determining whether the project should proceed to the next phase or to site closeout). The section highlights key nonrisk considerations and emphasizes the importance of integrating the ERA results and uncertainties into an overall risk management decision.

Section 9-3 discusses the design considerations for implementing an overall site remediation strategy. Such a strategy considers issues such as offsite source areas, current and future land uses, compliance with chemical and site-specific ARARs (EPA 19891). and verification of cleanup.

9.2 Determining Requirements for Action

The fundamental requirement associated with any HTRW response action is the "protection of human health and the environment." This requirement focuses on the acceptability of site risks from the potential actions. section 300.430 (d) and (e) of the NCP (55 FR 8660, March 8, 1990) and the proposed RCRA Corrective Action Rule (55 FR 30798, July 27, 1990) require a baseline risk assessment or environmental evaluation to be performed to assess threats to the environment.

Risk management options are exercised in key phases of the HTRW project life cycle (see Table 9-1). Risk information required to support a decision is presented below:

9.2.1 PA/SI and RFA

The purpose of PA/SI under CERCLA and the RFA under RCRA is to identify if chemical releases have occurred, or if the site can be eliminated from further action. The PAs and RFAs are typically performed by the state, EPA, or the Federal agency, and are generally preliminary in nature. Under some circumstances Federal agencies may perform these activities with greater depth and vigor under Executive Order 12580. Unless good evidence exists that a site is contaminated, it is a crucial for the PM or the TM to methodically review each identified site. area of contamination, SWMU, and AOC, and decide if these units should be eliminated from the next project phase. In addition, it may be important to determine if an environmental threat or a substantial site risk potentially exists that would requite. an early response action (e.g., non-time critical removal actions, interim measures, or interim remedial action).

9.2.1.1 Actual or Potential Release/Exposure

Under the PA/SI or RFA phase, the risk management decision will be based on documented past spills and releases, the likelihood of such spills/releases, the presence of endangered or threatened species, sensitive environments or resources to be protected, and the existence of transport mechanisms that could bring the chemicals in contact with these receptors.

9.2.1.2 Potential Natural Resource Damage Assessment (NRDA) Action

Under CERCLA Sections 104(b)(2) and 107(f)(2)(C), the lead agency for cleanup (e.g., DoD, EPA) must notify appropriate Federal and state trustees of natural resources of any discharges or releases that may have injured natural resources under their jurisdiction. The PM is responsible for coordinating all response activities with the natural resource trustees. The PM should also consult with the USDOI (i.e., USFWS), DOE, or Department of

[2] This chapter does not address comparative analyses of other environmental risks, i.e., risks from radon gas, cigarette smoking, exposure to ultraviolet light due to stratospheric ozone depletion, ingestion of pesticide-contaminated food products, etc. These risks, although they may be significant in terms of the total risk posed to human receptors at a Superfund or RCRA site, are not related to HTRW site response actions and are considered background risks which are addressed by other environmental laws and policies. This chapter, however, does address the importance of risk assessment inputs in setting priorities for resource management with respect to environmental cleanup under RCRA and CERCLA. In making site risk management decisions, the PM should be familiar with the statutory language/limitations regarding the application of funds under DERA, BRAC, and other HTRW response actions.

Table 9-1
The Potential Use of Risk Assessment Concepts/Procedures as a Risk Management Tool

Project Phase	**Objectives**	**Risk Management Options** m	**Product/Deliverable**
PA/SI, RFA	**Should the site be eliminated from further evaluation?** Identify sites with no release or insignificant release Site ranking/prioritization Need for removal action Need for RI or RFI	**NO FURTHER ACTION (NFA);** LIMITED SAMPLING/VER.; STAB, REMOVAL, RESP; LIMIT SCOPE OF RI/RFI; PHASED RI/RFI SAMPLING	**Chemical fate and transport properties.** Toxicity assessment (chemicals not expected to pose an ecological concern). Environmental mapping (sensitive receptors and food source identification). Exposure pathway analysis/food web and use of ECSM. Land use assessment.
RI, RFI	Does the site pose an ecological risk? Need for FS or CMS	NFA; MONITORING; INTERIM MEASURES/ INTERIM REMEDIAL ACTIONS; CONDUCT FS OR CMS	Baseline risk assessment. - Comparison with published criteria or benchmark toxicity values. - Toxicity-based ERA to assess stress-response relationship
FS, CMS	Preliminary Remediation Goals Select remedial alternatives	REMEDIAL ACTION OBJECTIVES; ONSITE/OFFSITE MANAGEMENT; NFA; MONITORING	Development of site-specific PRGs or benchmark toxtcity values. Assessment of short-term risks from remedial alternatives.
RD/RA, CMI	Protective control measures/remedy	EFFECTIVENESS AND DESIGN BASIS FOR CONTROLS TO REDUCE SHORT-TERM RISKS	Comparison with short-term acute risk levels. Exposure pathway analysis. Identification of impact areas, traffic patterns, and dis- charges.
Delisting/ site doseout	Residual risks & year review. permit review	NFA: MONITORING; RA OR CORRECTIVE MEASURES; ADDITIONAL FS AND RD	Land use/pathway analysis. Comparison with PRGs or RAOs Provide justifications for meeting cleanup objectives or technical impracticability.

Legend:

Technical Impracticability = technology not practical, e.g.. remediation of groundwater aquifer contaminated by dense non-aqueous phase liquids (DNAPL)

NFA = no further action
PRO = preliminary remediation goals
RAO = remedial action objective
RI/RFI = remedial investigation/RCRA facility investigation
SWMU = solid waste management unit
VER = verification

Commerce (DOC) where a discharge or release may adversely affect an endangered or threatened species or result in destruction or adverse modification of the habitat of such species. The trustees are responsible for assessing damages (i.e., monetary compensation) and presenting a "demand in writing for a sum certain" to the potentially responsible parties. Although the PA/SI or RFA is an early project phase and the potential for an NRDA action may not be known, the PM and the risk assessor should be cognizant of the potential when reviewing site history and background information. Any findings with potential implications for NRDA uncovered in this process should be provided to the customer and its legal counsel. This is recommended because the customer's goals for site close-out may be different upon further review of the potential for NRDA. By coordinating and working with Federal co-trustees, an overall remedial action (which might include restoration or mitigation) can be devised which will reduce an installation's NRDA liability.

9.2.1.3 Risk Screening and Prioritization of Units of Concern

Initial risk screening (Chapter 3) is an important tool for ranking or prioritizing units (OUs/SWMUs). This tool can result in substantial savings of resources, allowing the implementation of a more focused site investigation. The risk screening results are likely to provide significant inputs into the risk management decision-making for this project phase.[3]

It is not uncommon to have tens or hundreds of "sites" or SWMUs within a site or facility boundary. Risk managers at these facilities are faced with potentially complex investigations. Rather than taking a "piece meal" approach of investigation, the list of sites or SWMUs should be pared down if possible. The risk manager may negotiate with the agencies and enter in the IAG or FFA to permit the use of an approach that "addresses the worst sites first," and at the same time, group SWMUs within the same ecological receptor exposure units or geographical locations, as appropriate. This prioritization should result in the greatest environmental benefit with limited available resources. Site prioritization should include the following:

- Eliminate sites or SWMUs administratively by record review (including ascertaining if endangered or sensitive species/environment or valued resources are present on site), by interviews with current and former workers, and by ascertaining whether the unit of concern meets the definition of an "SWMU."

- Conduct a site reconnaissance and group sites or SWMUs with common exposure pathways or EUs, if appropriate.

- Rank the remaining sites or groups of sites qualitatively or quantitatively based on the ECSM or a screening risk analysis.

Generally, the above-listed tools will serve well if they are objectively and uniformly applied. The use of site prioritization:

- Provides justification for no further action (NFA) for low-priority sites.

- Allows better resource allocation for investigation of the remaining sites.

- Provides the opportunity to develop ECSMs to guide data collection (see Chapter 4).

- Helps identify potential boundaries where the ecological receptors of concern are to be protected.

- Identifies high-priority sites or SWMUs for non-time critical response actions.

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[3] EPA's Deputy Administrator (1994) is concerned with the need for ensuring consistency while maintaining site-specific flexibility for making remedial decisions (from site screening through final risk management decisions) across programs. EPA stresses that priority setting is reiterative throughout the decision-making process because limited resources do not permit all contamination to be addressed at once or receive the same level of regulatory oversight. EPA suggests that remediation should be prioritized to limit serious risks to human health and the environment first, and then restore sites to current and reasonably expected future uses, whenever such restorations are practicable, attainable, and cost effective. EPA further suggests that in setting cleanup goals for individual sites, we must balance our desire to achieve permanent solutions and to preserve and restore media as a resource on the one hand, with growing recognition of the magnitude of the universe of contaminated media and the ability of some cleanup problems to interact with another.

DoD's (1994b) *Relative Risk Site Evaluation Primer* recommends evaluation based on three criteria: (1) contaminant hazard factor; (2) migration pathway factor; and (3) receptor factor (Figure 9-4). Information generated from the initial ecological risk screening (Chapter 3) can be used as a decision-malting basis using a similar site ranking process. Sites may be ranked high, medium, or low based on nonquantitative exposure pathway considerations such as the following:

(A) Significant Contaminant Levels

1. High Relative Risk Sites with complete pathways (contamination in the media is moving away from the source) or potentially complete pathways in combination with identified receptor or potential receptors.

2. Low Relative Risk: Sites with confined pathways (i.e., contaminants not likely to be released or transported) and limited potential for receptors to exist.

3. Medium Relative Risk: Sites with characteristics not indicated in the above.

(B) Moderate Contaminant Levels

1. High Relative Risk: Sites with complete pathways or potentially complete pathways in combination with identified receptor or sites with complete pathways in combination with potential receptors.

2. Low Relative Risk: Sites with confined pathways and any receptor types (i.e., identified, potential, or limited potential), or sites with potentially complete pathways in combination with limited potential for receptors to exist.

3. Medium Relative Risk; Sites with characteristics not indicated in (B)(l) and (B)(2) above.

(C) Minimum Contaminant Levels

1. High Relative Risk: Sites with complete pathways in combination with identified receptor.

2. Medium Relative Risk: Sites with potentially complete pathways in combination with identitied receptor or sites with evident pathway in combination with potential receptors.

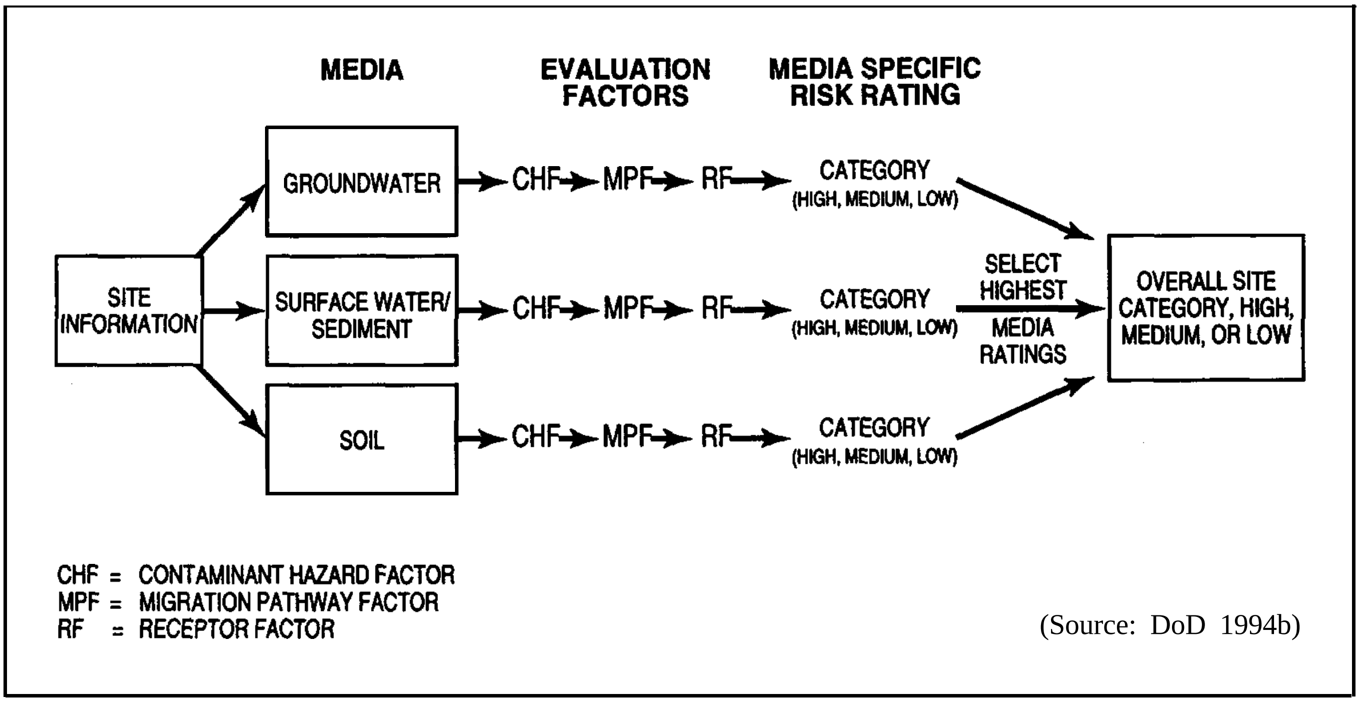

Figure 9-4. Flow diagram of relative risk site evaluation framework

3. Low Relative Risk: Sites with characteristics not indicated in (C)(2) above.

9.2.1.4 Risk Management Decisions and Options

Risk management decisions, risk information needs, risk assessment tools to satisfy the information needs, and risk management options are presented in this section. "Non-risk" factors to be considered in the decision-making are presented in Section 9.2.4.

Risk Management Decision

- Should a site be eliminated from further investigation in the RI or RFI project phase?

Risk Management Options/Rationale

- Further Evaluation Needed

Rationale: If a site cannot be justified for NFA. further evaluation (Expanded SI: Extent of Contamination Study: RI or RFI) will be needed.

- No Further Action (NFA)

Rationale:

- Environmental mapping, functional group characterization, database searches, or published lists from natural resources agencies indicate that endangered species are not present, and there are no sensitive environments or valued resources on and nearby the site.

  - No knowledge of documented releases or major spills/low likelihood of spills/procedures existed to promptly clean up all spills.

  - Transport mechanisms do not exist, e.g., presence of secondary containment.

  - The substances released are not expected to be present due to degradation and attenuation under the forces of nature.

- Spills or releases have been addressed by other regulatory programs (e.g., the Underground Storage Tank (UST) program or RCRA closure under Subpart G of 40 CFR 264 or 265).

  - The unit does not meet the definition of an "SWMU."

- The unit is part of another identified unit or site which will be addressed separately.

Although risk assessment is traditionally performed in the RI or RFI project phases of HTRW response actions, risk assessment can assist the risk managers in all project phases. Results of risk assessment activities are used to answer three key questions: I) whether or not there is a need to go forward with the next project phase, 2) whether or not early response actions (removal actions, interim measures, or interim remedial actions) should be taken to mitigate potential risks, and 3) effectiveness of the potential response action and the short-term risks associated with implementation of the removal actions.[4] Providing an understanding of the usefulness of risk assessment in the HTRW removal phase is the focus of this section.

Risk Management Decision

- Should early response action be undertaken to mitigate risk?

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[4] Removal actions must be flexible and tailored to specific needs of each site and applicability, i.e., complexity and consistency should be used in evaluating whether non-time critical removal actions are appropriate. Examples of removal actions are: (1) sampling drums, storage tanks, lagoons, surface water, groundwater, and the surrounding soil and air; (2) installing security fences and providing other security measures; (3) removing and disposing of containers and contaminated debris; (4) excavating contaminated soil and debris, and restoring the site, e.g., stabilization and providing a temporary landfill cap; (5) pumping out contaminated liquids from overflowing lagoons: (9 collecting contaminants through drainage systems, e.g., French drains or skimming devices: (7) providing alternate water supplies: (8) installing decontamination devices, e.g., air strippers to remove VOCs in residential homes; (9) evacuating threatened individuals, and providing temporary shelter/relocation for these individuals (Superfund Emergency Response Actions, EPA 1990f). Items (3) through (5) could be used to reduce exposure to ecological receptors of concern.

Risk Management Options/Rationale

- No Early Response Action

  Rationale:

  - No imminent endangerment to ecological receptors of concern; lack of food sources to support or attract ecological species, lack of endangered species or sensitive environment/ valued resources, low likelihood of exposure by the receptors. (Uncertainty for the determination is related to thoroughness by the record search, visual observation, or purposive limited sampling.)

  - Transport mechanisms probably do not exist, e.g., presence of secondary containment.

  - Low concentration of site contaminants or the levels measured probably do not pose an acute hazard, and it is questionable whether the levels pose unacceptable chronic risk or hazard.

  - There is no anticipated risk of stress or physical hazards.

  - Site contaminants are not likely to be persistent or the contaminants are relatively immobile.

- Early Response Action

  Rationale:

  - There is no current impact, but if uncontrolled, the site could pose a substantial threat or endangerment to humans or the environment. (Examples ate: physical hazard, acute risk from direct contact of the unit or site, or effluents or contaminated media are continuously being discharged to the a sensitive environment, e.g., a spill that could impact salmon spawning, egg hatching, or survival of fry.)

  - The principal threat has reasonably been identified because of the evidence of adverse impacts. In this context, the COECs are known and the exposure pathways are judged to be complete, e.g., the exposure point or medium has been shown to contain the COECs.

  - Due to the slow rate of degradation, excretion, or depuration. the potential COECs may pose a threat to the food web via bioconcentration and biomagnification.

  - The boundary of contamination is reasonably well defined. so that removal action(s) can be readily implemented.

  - There is a potential risk to ecological receptors or valued resources and the removal or early response actions have been demonstrated to be highly effective in reducing exposure to ecological receptors of concern, although candidate removal actions may differ in terms of cost and magnitude of risk reduction achieved.

  - The early actions are consistent with the preferred final remedy anticipated by the customer, reducing risks to both human and ecological receptors.

  - The response action will be used to demonstrate cessation or cleanup of releases, resulting in substantial environmental gain which is the basis for early site closeout or further investigation.

  - If removal actions ate justified (e.g. addressing hot spots or high concentration plumes discharging to a receiving body of water with sensitive aquatic species, food chain, or valued resources), the removal actions will then be evaluated for their potential short-term risks and hazards, based on ECSM developed for the specific removal actions.

  - A high likelihood of releases and transport of site contaminants to the ecological receptors of concern, e.g., runoff from the site is expected to reach a receiving body of water containing endangered species or valued resources.

  - High concentration (acute hazard level) of site contaminant is found in the exposure medium.

  - Highly toxic chemicals or highly persistent and bioaccumulative chemicals found onsite which may be transported offsite.

- Documented unacceptable sediment, soils, surface water, or groundwater seep contamination in media that could be contacted by endangered species.

- Ecological impacts have been observed due to volume of the release and the habitat destruction of valued resources.

- A high risk of physical hazards or stress to the environment.

- The exposure pathway(s) for ecological species was the reason or one of the reasons for the basis for NPL listing or ongoing enforcement actions on spills or releases.

- Noncomplex site (no cost recovery issue, limited exposure pathways, small area sites, etc.)

Early response actions or removal actions, consistent with the final remedial action, may be taken to prevent, limit, or mitigate the impact of a release+ To encourage early site closeout or cleanup, EPA has encouraged early response actions at sites where such actions are justified. To the extent possible the selected removal actions must contribute to the efficient performance of long-term remedial actions. EPA's *RCRA Stabilization Strategy* (EPA 1992m) and *Superfund Accelerated Cleanup Model* (SACM) (EPA 1992n) emphasize controlling exposure and preventing further contaminant migration. While these concepts are intended to expedite site actions, risk assessment provides important information for justifying cleanup actions. The applicable risk assessment methods include:

- Environmental mapping/functional assessment.

- Exposure pathway analysis: development of ECSM.

- Identifying short-term (acute) benchmark toxicity values for screening site data.

- Qualitative evaluation of removal actions for their effectiveness to reduce exposure to ecological receptors.

- For complex sites (sites with multiple pathways, without ARARs, large geographic areas, and with a need for cost recovery), activities to support a baseline ERA may be appropriate.

In order to allow input for the removal actions, the risk assessment should be conducted in a timely manner. As an initial and highly conservative screening tool, comparison of worst-case exposure point concentrations can be compared with short-term (acute or subchronic) ecological benchmark values. Such risk evaluation should be qualitative, simple, and concise.

Early actions or accelerated cleanup can often be justified as long as the actions are consistent with the preferred site remedy. Since remedies am generally not selected until late in the FS or CMS, the customer's concept of site closeout and anticipated action is critical for deciding which types of early actions are appropriate. Based on experience gained in the Superfund program, EPA has identified certain site types where final remedies are anticipated to be the same (presumptive remedies). The current list of presumptive remedies includes:

- Municipal Landfill -- capping and groundwater monitoring.

- Wood Treatment Facility - soil and groundwater remediation.

- Groundwater contamination with VOCs - air stripping/capture wells.

- Soil contamination with VOCs - soil vapor extraction.

Additional presumptive remedies are being developed by EPA Region VII for PCB sites, manufactured gas plants, and grain fumigation silos. EPA is continuing to identify site types for which early actions are likely to result in substantial environmental benefits. However, it should be noted that certain sites are not conducive to early actions based on ecological concerns. Examples can include where: current and future. land use is highly industrial; there is a lack of food sources onsite or nearby the site for the ecological receptors of concern; there is low or generally low-level, widespread contamination; spilled or released substances are not bioavailable: contaminants have short halve-lives or are anticipated to degrade rapidly under natural conditions; there is a lack of viable environmental transport media (highly arid regions).

9.2.1.5 Qualitative Evaluation of Response Actions for Their Effectiveness to Reduce Risks

Removal of hot spots can provide substantial improvements in the site environment. In some cases, actions can reduce exposure to receptors drastically, and allow natural attenuation to further reduce exposure point concentration. If removal actions are needed, the risk manager should request two types of risk information. First, if there is more than one removal option, what is the comparative effectiveness of the options to reduce exposure and risks? Second, what is the risk or environmental impact associated with the. proposed removal action? To answer the first question, the HTRW risk assessor or risk manager provides information on bow the removal option can eliminate risk or reduce the level of exposure both onsite and offsite, if contaminant migration has occurred at offsite exposure. points. If substantial risk reduction can be obtained by all options, the risk manager should consider other factors, such as effectiveness, reliability, etc. To answer the second question, the project engineer estimates the destruction or treatment efficiency of the medium to be treated or disposed, and the type/quantity of wastes or contaminated debris to be generated for each potential option. This information is important if an action is likely to generate waste or damage sensitive environments in the course of the remediation.

It is important to communicate and obtain an early buy-in of the removal action from the local community. If the proposed removal actions are likely to pose unacceptable short-term risks to onsite or offsite ecological receptors, the removal action should either be discarded or monitoring/control measures be instituted. (As discussed later, the risk assesor and HTRW technical project planning team members provide options for making decisions when there are divergent interests between the protection of humans and the protection of ecological receptors of concern.) The risk assessor should work with other project team members to evaluate the potential for chemical releases or habitat destruction potentially associated with a remedial option. These evaluations should be qualitative and not extensive, and can be based on a consensus of professional judgment/opinion. These individuals should recommend alternatives or precautionary/protective measures to the risk manager to mitigate any potential risks.

9.2.2 RI/RFI

The primary objective, of RFI, RI, or other equivalent HTRW project phases is to determine if site contamination could pose potentially unacceptable human health or environmental risks. Determination of unacceptable risk, according to the NCP, is identified through a baseline risk assessment under "Reasonable Maximum Exposure." The RCRA corrective action process is similar to Superfund for determining the need for remediation, albeit initially, the TSDF owner/operator may simply compare a specific set of SWMU data with established AWOC or literature effect range levels. The proposed corrective action rule does not provide additional guidance on how action levels are to be developed for other media based on ecological concern. ERA generally considers performance of a Health and Environmental Assessment (HEA) to be functionally equivalent to the Superfund baseline risk assessment (human health and ERA) in the RI/FS while a few ERA regions have developed ERA guidelines for RCRA. The RCRA HEA should be conducted prior to or early in the CMS to determine the need for corrective measure implementation.

The ERA or HEA associated with the RI/RFI project phase can assist the risk management decision-making process in the following ways:

- The ERA presents the degree of site risk posed to ecological receptors and the associated uncertainties. Risks are generally assessed based on individual effects, although effects on populations and communities may be studied in the Tier IV assessment. Risks can be estimated for the entire site. OUs, AOCs, SWMUs, or CAMUS.

- Results of the ERA can be used to answer questions relating to the site decisions on: 1) whether sufficient information exists to confidently eliminate a site as posing no significant risk or there is a need to proceed to the next project phase; and 2) whether or not removal actions are still appropriate and should be implemented to mitigate potential ecological risks.

- If a site poses unacceptable acute or chronic hazard to ecological receptors, remediation will be needed for the significant exposure pathways. Pathways which do not pose an unacceptable risk may be eliminated from further concern. Algorithms developed in the ERA can be used in reverse to develop site-specific environmental-based preliminary remediation levels in the FS.

- If removal actions ate still appropriate and are to be implemented, the short-term impact of such actions should be evaluated.

Risk Management Decision

- Should remedial action or corrective measure be required based on the baseline ecological risk?

Risk Management Options/Rationale

- Further Evaluation Needed

  Rationale: The ERA indicates unacceptable risk or the risk cannot be confidently established, and therefore the customer has weighed all options and determines the uncertainty associated with the ERA should be reduced. Further evaluation and/or data evaluation is needed to reduce uncertainty and determine ecological risk. Since risk assessment is an iterative process, data used to support the risk estimates should be critically reviewed by the PM. The review may lead to the need for additional data to more fully characterize potential risk. Alternatively, the manager may ask for a more detailed analysis of uncertainties so that the decision for remedial action can be made.

- Undertake Interim Response Action

  Rationale: Action is based on finding of unacceptable risk to ecological receptors, after giving consideration to the uncertainties associated with the ERA. The selected interim remedial action or interim measure should be. part of or is consistent with the final anticipated remedy or corrective measure..

- No Further Action (NFA)

  The rationale for no action based on the ERA could be any (or a combination) of the following:

  Rationale:

  - Documentation that endangered species or sensitive environments are not going to be impacted by the site due to the lack of complete exposure pathways, or the impact is judged to be insignificant or acceptable by the risk assessor and/or expert ecologist(s)/advisory panel such as BTAG/ ETAG.

  - Lack of habitat or food sources to support the ecological receptors of concern and potential offsite migration of site-related COECs to any nearby habitats or food webs of concern is negligible, or site land use will remain industrial/ commercial based on stakeholder's inputs.

  - The HQ is below unity or ten, as appropriate, based on uncertainty of the toxicity data (or the frequency of exceedance of this point of departure value is low). given the uncertainty inherent in the ERA involving multiple surrogate or indicator species (measurement endpoints).

  - An existing ERA has been revised, reflecting that removal actions or interim measures taken have substantially reduced the exposure to the level that the estimated risks am acceptable.

  - The potential environmental risk or injuries associated with any and all remediation is grater than the baseline risk (i.e., further efforts should be expended to find a suitable remedial action or viable alternatives, such as offsite mitigation, restoration, or compensation).

  - With source control in place, given natural attenuation of the COECs (based on fate and transport properties), risk is expected to be short-term, and remediation is judged to be cost-prohibitive.

  - There could be marginal risks: however, considering uncertainties, the potential incremental gain does not justify the action.

  - No practical remedial action objectives or target cleanup levels can be established to sufficiently document risk or such levels would be highly uncertain and the environmental gain cannot be readily measured.

  - Potential remedy will cause substantial economic or scenic damage and is not consistent with the public and stakeholders' goals and objectives.

  - Interim remedial action or interim measures have removed the migration/transport mechanisms to impact ecological receptors.

  - Site contaminants are not likely to ever pose unacceptable risk as they am not persistent or the contaminants are relatively immobile and not bioavailable.

- Remediation/Removal Action Required.

  The requirement for removal action taken at the RI/FS or RFI/CMS project phase is the same as that described under Section 9.2.1.4 above. Upon completion of RI/FS (and before signing of the Superfund Records of Decision or the completion of RCRA Part B permit modification), a decision will be made whether remedial action or RCRA corrective measure implementation should be. required. If there are site ARARs, such as state water quality standards, remediation will be required unless an ARAR waiver is successfully completed. From the risk assessment standpoint, if the baseline ERA is valid and the uncertainty deemed to be acceptable, requirements for remediation for part of or the entire site will be based on the following considerations:

- Endangered species or sensitive environments/ valued resources such as viable wetlands or wildlife refuge could be impacted by the site, and the estimated risk is judged to be significant or biologically relevant.

- Viable habitat and sufficient food sources are available to sustain the ecological receptors of concern.

- The COECs are persistent or bioaccumulative and will potentially impact ecological receptors of concern.

- The site poses an unacceptable risk.

- The environmental risk associated with the remedial action or the corrective measure implementation is acceptable.

- Short-term impacts from remediation, although potentially severe, are not permanent and outweigh the alternative of long-term, chronic exposure.

- COECs are persistent and expected to pose a long-term threat to the ecological receptors of concern.

- The remedial action objective (RAO) or target cleanup level (TCL) is based on a reliable or adequately characterized exposureresponse relationship and is practical for use to verify cleanup and the environmental gain is measurable.

- There is a low potential for recovery without removal or remedial actions.

- Remediation is consistent with the stakeholders' goals and objectives.

9.2.2.1 <u>Risk Characterization/Uncertainty Information for RMDM</u>

The sources of uncertainties in a Tier I baseline ERA were presented in Chapter 4. The objective of the risk characterization and uncertainty analysis is to make the ERA transparent to the risk managers and the stakeholders so that informed risk management decisions can be made. Given proper early project planning, it is expected that uncertainties will be acceptable to the risk managers and other stakeholders, including the BTAG members and other independent expert ecologists. The risk manager can balance his or her selection of options with the findings of the risk assessment and the degree of uncertainty in mind.

From the risk manager's perspective, the baseline ERA should adequately present risk estimates in an objective and unbiased manner. The risk manager or PM understands that although the risk assessment is a scientific tool, the results cannot be easily used to determine specifications. Moreover, it is a tool for risk management decision-making, and is rarely a tool for the prediction of actual occurrence of environmental effects. Therefore, as long as the uncertainties are presented and understood by the customer and other decision-makers, the results can be accepted or rejected for use in site decisions.

When making site decisions, the risk manager or PM can substantially benefit from consultation with responsible technical experts (risk assessors, expert ecologist[s]/ advisory panel [BTAG/ETAG]). It is the responsibility of these experts to document and present uncertainties so the risk manager or PM makes an informed decision. In the final baseline ERA, the risk assessment summary presents risks and the associated uncertainty information in a weight-of-evidence discussion which focuses on strengths and weaknesses of the risk estimates, providing information to assist in determining the overall objectives and decisions to be made in this project phase.

In order to make informed risk management decisions, the risk manager should have a clear understanding of the following:

- What are the receptors or resources to be protected?

- Does the ecological risk involve individual organisms, communities, populations, or different trophic levels?

- What is the aggregate hazard index (HI)?

- How do effects or ecosystem characteristics between the site and the reference locations compare.?

- What is the likelihood of recovery based on consideration of the contaminants' fate and transport properties, the substrate or media characteristics, natural attenuation, and lessons learned from similar sites?

- How do hazards under RME and average (typical) exposure compare? What are the "or&r of magnitude" differences?

- What is the key and overall uncertainty of the baseline ERA in terms of chemical data, COEC selection, exposure assessment and modeling, toxicity information, and characterization method? Is uncertainty quantifiable to the extent that the TCLs could be substantially altered?

- If the risk estimates are unacceptable, will quantitative analysis of uncertainty be able to demonstrate that the risk estimate is based on overly conservative assumptions, i.e., in the theoretical upperbound range?

- What are the COBC(s) and exposure pathways that constitute the principal threat?

- How are the exposure units defined in the baseline ERA?

- Are there any "hot spots" which would require further characterization. or removal action?

- Are there any acute hazards or risks which will require emergency response or removal action? Is there a risk of further spills, releases, or physical hazards that could further degrade the environment or adversely impact the ecological receptors of concern?

- If removal or early response actions are desirable, how effective are the proposed removal actions to reduce site risk?

- Which are the anticipated or preferred options for actions?

9.2.3 FS/CMS and RD/RA

The FS or CMS is triggered when the baseline risk is unacceptable and remediation is needed to mitigate risks and prevent further contaminant migration, In some instances, the FS or CMS could be driven by a legal requirement to meet ARARs, although ARARs are not necessarily risk-based The FS or CMS evaluates potential remedial alternatives according to established criteria in order to identify the appropriate remedial alternative(s). The FS or CMS can be performed for the entire site or any portion of the site that poses unacceptable risks. The results of the FS/CMS include recommendations for the risk managers or site decision-makers, including an array of remedies for selection, RAOs, or TCLs for verification of cleanup.' The selected remedies/TCLs or revisions thereof will be entered into the ROD or the Part B permit.

Risk Management Decision

- What are the Remedial Action Objectives (ROAs)?

Risk Management Options/Rationale

The risk management decision for selection of final remedies depends substantially on the RAOs. Uses of RAOs are summarized below:

- Developed or agreed upon by the agencies prior to the FS or signing of the ROD (or modification of the RCRA permit), RAOs are used to evaluate the feasibility of candidate remediation technology in the FS;

- Initial estimation and costing of remediation (e.g., excavation and stabilization);

- Delineation of cutlines for remediation:

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[5] For the purpose of protecting the environment, the TCLs, sometimes known as RAOs, may be the same as the environmental-based preliminary remediation levels, or they may be different. TCLs or RAOs are negotiated levels for verification of cleanup and take into consideration performance of the proposed cleanup technology, practical quantitation limits, and uncertainties associated with the preliminary remediation levels to protect ecological resources of concern.

- For use in negotiation or final determination of specific areas, SWMUs, or site-wide cleanup goals, by considering uncertainties, technology, and cost.

Before embarking on an FS, RAOs should be developed using site-specific risk information consistent with site conditions. Factors to be cons&red when RAOs are used as the basis for designing and implementing remediation are presented below:

9.2.3.1 Remedial Action Objectives Must be Based on ECSM

The ECSM provides the framework for the baseline ERA and identifies the specific pathways of concern. RAOs must be able to address these pathways and the associated risks. A refined ECSM, based on the results of the ERA, is paramount to the establishment of focused RAOs. The RAOs are based on preliminary remediation levels developed as the project strategy goals in Phase I of the HTRW project planning under RI/FS or RFI/CMS.

9.2.3.2 Remediation Goals Must be Protective and Practical

Remediation goals are performance and numerical objectives developed in the FS/CMS to ensure that the remedial alternative will contribute to site remediation, restoration, and closeout/delisting. As such, they must be protective and workable. To ensure protectiveness, risk-based preliminary remediation goals should be first derived using the screening or baseline ERA procedures in reverse (see procedures described in Chapter 8). The uncertainty associated with development of the remediation goals should be discussed and quantified Preliminary remediation levels can be derived early in the site investigation process or at the end of the RI, when it is determined that remediation may be needed because of unacceptable risks. Site decision-makers carefully consider technology, practical quantitation limits, ARARs or to-be-considered criteria, reference location concentrations, acceptable hazards, field or laboratory analytical uncertainties, etc., before setting the RAOs.[6]

9.2.3.3 Action Must Be Consistent with Other Project Phases

Understanding of the nature and extent of contamination, as well as the media and exposure pathways of concern, is a critical requirement for successful completion of the FS or CMS and remedy selection. Therefore, data used in the FS or CMS must interface with the RI/RFI and other previously collected site data. Inadequate data or data of poor quality m&present site contamination and may lead to an inadequate baseline risk assessment and FS. For each exposure pathway that presents an unacceptable ecological risk, the risk assessor and the appropriate project team members (e.g., chemist, geologist, or hydrogeologist) should review the RI data before conducting the. FS. This is particularly important when the FS is performed simultaneously with the RI, based on assumptions and PA/SI or RFA data.

RAOs may be selected based on one of the following:

- Background

  Rationale: The environmental concentrations at the reference area or upgradient area will be used as RAOs since the ecological receptors or the valued resources to be protected are also located at the background locations. The reference area has the same current land use as the site and the levels are reasonable and attainable.

- RAOs are performance-based

  Rationale: No reasonable chemical-specific cleanup level can be derived due to high uncertainty in the hazard-response relationship. For the purpose of remedy selection, the best available or best demonstrated remedial technology will be utilized to achieve certain risk reduction objectives according to the ECSM.

- Risk-based Remediation Go& (Cleanup GO&).

  Rationale: In lieu of performance-based RAO or cleanup to the levels at the reference area risk-based RAO can be developed using dose-response information for the ecological receptor of concern or its surrogate species. The risk-based RAOs may be

[6] Certain sites may be. contaminated with natural or anthropogenic substances which pose matrix interferences and cause high sample detection limits, i.e., the practical quantitation limits (PQLS) may be higher than the environmental-based preliminary remediation levels. For these sites, it may be advantageous to design a representative sampling program of the background medium to establish PQLs for use as alternative remediation goals.

adjusted upward or downward according to other risk management factors or considerations.

Minimal information or guidance has been developed by EPA regarding the development of RAOs for RCRA and Superfund sites. RCRA has issued the Alternative Concentration Limit (ACL) Guidance based on 40 CFR 264.94(b) criteria and case studies (EPA 1988j) which may be applied to developing ACLs at the source if the acceptable groundwater/surface water mixing zone concentrations and the dilution/attenuation factors are defined. Under the. proposed subpart S rule for RCRA corrective action, the state water quality criteria can be used to screen if a CMS should be conducted. For the protection of aquatic receptors, cleanup levels can be set to chemical-specific water quality criteria. Nonetheless, the key risk management issue concerning the above is that the cleanup goals must be practical and verifiable. When cleanup goals ate developed to protect both humans and ecological receptors, according to Section 300.340 of the NCP. the goals must be so adjusted that both receptor types are. protected.

Environmental and human health-based RAOs should be developed together and proposed to the risk manager and agencies for use in the CMS for the evaluation of remedial alternatives. It should be noted that the RAOs may have to be revised or refined based on other considerations, e.g., technology, matrix effects, target risks, uncertainties, and costs (associated with the extent of the remediation, management of remediation wastes, and cost of cleanup verification analyses).

Risk Management Decision

- **What are the Remedial Alternatives or Corrective Measures?**

- **What are the Preferred or Optimal Remedial Alternatives?**

Risk Management Options/Rationale

In addition to a cost and engineering evaluation of the potential remedial alternatives, each alternative must be evaluated for its ability to reduce site risk. Among the nine criteria identified by the NCP for remedy selection, protection of human health and the. environment and satisfying ARARs are considered to be the threshold (fun&-mental) criteria which must be met by any selected remedy. More recently, EPA has placed increased emphasis on short- and long-term reliability, cost, and stakeholders' acceptance in the overall goal to select remedies. Therefore, the assessment of residual risk (a measure of the extent of site risk reduction) is a critical task.

Screening and detailed analyses of remedial alternatives will be conducted in the FS and CMS project phase. The preferred remedial alternative will be proposed. As warranted, analysis of short-term risks to assess the need for control measures will be conducted in the RD project phase, and the control measure(s), if appropriate, will also be proposed.

In the FS, potential risk reductions associated with remedial alternatives am assessed. The relative success of one alternative over another is simply the ratio of the residual COEC concentrations in the exposure medium of concern. This screening evaluation does not take into account short-term risks posed by the alternative or technology due to acute hazards, releases, or spills.

9.2.3.4 Screening Evaluation of Alternatives

This evaluation focuses on determination of short-term risks posed by the removal or remedial alternatives. The findings of this evaluation are compared among the alternatives to determine preferred remedies based on the effectiveness of the remedies to satisfy remedial action goals with the least environmental impact. This screening evaluation should focus primarily on effectiveness, risk reduction, and cost.

Risk screening of alternatives should generally be qualitative or semiquantitative. If a remedy has already been selected or is highly desirable for selection, a detailed risk analysis may not be needed. Instead, the evaluation should focus on the risk reduction of the preferred remedy, and identify any concerns or data gaps which need to be addressed. The data needed to perform this screening evaluation may come from many sources: RI or RFI data, bench scale or pilot scale treatability studies conducted for the site or from comparable sites, compatibility test, test of hazardous characteristics, field monitoring measurements, vendor's or manufacturer's information, literature values, and professional judgment.'

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7 The bench sale or pilot scale treatability studies may provide valuable information for the estimation of remediation action or residual risks. Treatability studies provide data or information on the degree of removal and/or destruction of the COECs. quantity and identity of chemicals in the emissions or effluent discharges. and potential treatment standards to be applied to satisfy remedial action goals. This information is important to quantify the magnitude of risk reduction and will be useful in the comparative analysis of potential remedial alternatives.

Key information needed prior to conducting the screening evaluation of remedial alternatives include:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up, and shut-down operations).

- Toxicity of chemical substances or COECs in the above discharges.

- Potential for dilution and attenuation.

- Existence of exposure pathways and likelihood of the pathways to be significant and complete.

- Potential for spill or releases during remediation, material handling, storage, and transportation of remediation wastes.

- Potential for the causation of nonchemical stressors such as destruction of critical habitat for threatened and endangered species, wetlands, or other sensitive environments, increased siltation and reduction of food sources for the ecological receptors of concern or other receptors/valued resources.

- Temporal attributes associated with a remedial action which could be altered to reduce the action's impact.

- Potential release of additional COECs to the environment (e.g., re-suspension of toxic sediments during dredging, and changes of pH, redox potential, oxygen, and chemical state that may increase solubility and bioavailabitity).

The following are lists of qualitative evaluation criteria:

- Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).

  - Able to remove, contain, or effectively treat site COECs.

  - Able to address the exposure pathways and media of concern.

  - Able to meet the remedial action and overall project strategy goals.

- Assessment of Residual Risk Potential.

  - Reasonable anticipated future land use (for example, if the site remains industrial/ commercial in a foreseeable future, residual risk assessment should not be performed for the potential return of and exposure to terrestrial receptors).

  - Quantity of residues or discharges to remain on site.

  - Toxicological properties of the residues.

  - Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities. vapor pressure, density, etc.).

  - Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).

  - Potential for dilution and attenuation for residues released into the environment.

  - The extent of and permanence of remediation habitat destruction and alteration; for example, the construction of an access road through wetlands would be considered permanent.

9.2.3.5 <u>Detailed Analysis of Alternatives</u>

Detailed analysis is usually conducted for the preferred remedial alternatives (or removal actions) identified in the screening evaluation described above. This detailed analysis has three objectives: (a) detailed assessment of potential short-term risk during remedial action, and residual risks if appropriate; (b) assessment of the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives; and (c) identification of potential risk mitigation measures for the preferred remedies. The findings of these tasks are presented for final selection of remedies prior to ROD sign-off or RCRA Part B permit modification. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

Key information needed prior to conducting the screening evaluation of remedial alternatives include:

- Identity and quantity of emissions, effluent, byproducts, treatment residues, which may be released to the environment (during normal, start-up, and shutdown operations).
- Toxicity of chemical substances or COECs in the above discharges.
- Potential for dilution and attenuation.
- Existence of exposure pathways and likelihood of the pathways to be significant and complete.
- Potential for spill or releases during remediation, material handling, storage, and transportation of remediation wastes.
- Potential for the causation of nonchemical stressors such as destruction of critical habitat for threatened and endangered species, wetlands, or other sensitive environments, increased siltation and reduction of food sources for the ecological receptors of concern or other receptors/valued resources.
- Temporal attributes associated with a remedial action which could be altered to reduce the action's impact.
- Potential release of additional COECs to the environment (e.g., re-suspension of toxic sediments during dredging, and changes of pH, redox potential, oxygen, and chemical state that may increase solubility and bioavailability).

The following are lists of qualitative evaluation criteria:

- Risk Reduction Attributes (environmental protection, permanence, and toxicity reduction).
  - Able to remove, contain, or effectively treat site COECs.
  - Able to address the exposure pathways and media of concern.
  - Able to meet the remedial action and overall project strategy goals.
- Assessment of Residual Risk Potential.
  - Reasonable anticipated future land use (for example, if the site remains industrial/ commercial in a foreseeable future, residual risk assessment should not be performed for the potential return of and exposure to terrestrial receptors).
  - Quantity of residues or discharges to remain on site.
  - Toxicological properties of the residues.
  - Release potential of residues based on their fate/transport properties (e.g., log octanol/water partition coefficient, water solubilities, vapor pressure, density, etc.).
  - Properties or characteristics of the environmental medium which facilitate transport (e.g., hydraulic conductivity, organic carbon contents, wind speed and direction, etc.).
  - Potential for dilution and attenuation for residues released into the environment.

9.2.3.5 <u>Detailed Analysis of Alternatives</u>

Detailed analysis is usually conducted for the preferred remedial alternatives (or removal actions) identified in the screening evaluation described above. This detailed analysis has three objectives: (a) detailed assessment of potential short-term risk during remedial action, and residual risks if appropriate: (b) assessment of the potential for the risks to be magnified due to simultaneous implementation of this and other preferred alternatives: and (c) identification of potential risk mitigation measures for the preferred remedies. The findings of these tasks are presented for final selection of remedies prior to ROD sign-off or RCRA Part B permit modification. All preferred remedies or options should satisfy remedial action goals and should pose minimum health and environmental impact.

This evaluation may be qualitative. semiquantitative, or quantitative. If the analysis is quantitative, procedures and approaches similar to the baseline risk assessment may be followed. EPA's (1995g) *Air/Superfund National Technical Guidance Study Series* includes documents providing guidance for rapid assessment of exposure and risk. For example, guidance on determining the volume of soil particulates generated during excavation is provided in *Estimation of Air Impacts for the Excavation of Contaminated Soil* (EPA 19920). The data sources used to perform this risk analysis task should be similar to those identified for the screening evaluation of remedial alternatives. Although it is conceivable that the level of effort required for this analysis may be high (particularly, if the same analysis has to be performed for a number of preferred remedies), it is anticipated that the documentation and report writing will be focused and streamlined

The report should focus on the risk analysis approaches, sources of data, findings/recommendations for risk mitigation measures, and appendixes. Key factors or criteria to be considered in the screening evaluation of remedial alternatives are:

- The criteria or considerations in the assessment of short-term and residual risks are substantially similar to those identified for the screening evaluation of remedial alternatives. The key difference may be additional use of quantitative data input into the risk calculations, e.g., sediment transport modeling to evaluate the potential for migration of toxic sediment, amount of discharges or emissions, dilution/attenuation or atmospheric dispersion factors, exposure frequency, duration, and other activity patterns which could impact existing flora and fauna in time and space, and any indirect effects such as food source reduction and the extent of habitat destruction/alteration.

- Time required and extent of recovery from exposure to the above COECs and nonchemical stressors.

- The potential for fire, explosion, spill, and release of COECs from management practice of excavated or dredged materials should remain qualitative or semiquantitative. Fault-tree (engineering) analysis for accidental events may be attempted under special circumstances (e.g.. to address public comments or if demanded by citizens during public hearing of the proposed remedies).

9.2.3.6 Risks from Simultaneous lmplementation of Preferred Remedies

- Common exposure pathways for effluent or discharges from remedies.

- Period of exposure to the ecological receptors of concern via the common locations, time, and pathways.

- Sensitive environments and other threatened or sensitive wildlife or aquatic populations.

- Risk estimates or characterization results.

- Toxicological evaluation for the validity of biomagnification and additivity of risk (e.g., under the Quotient Method), based on literature review, mode of action. and common target organs, etc.

- Qualitative or quantitative assessment of potential short-term or residual risks.

Short-Term Risks Associated with Construction; the Design Risk Analysis. All removal or remedial alternatives have a potential to pose short-term risks to onsite mitigation workers, ecological receptors, and offsite humans. Risks may be associated with vapors, airborne particles, treatment effluent, resuspension of sediment resulting in an increase in the total suspended solids (TSS) or siltation of substrate for macroinvertebrates, and residues generated during operation of the remedial alternative. Therefore, all the alternatives should be reviewed for their short-term risks in conjunction with data from their bench scale or pilot scale treatability studies or data from implementation of the remedy at comparable sites. The risk assessor should estimate the period of recovery from these short-term insults and determine if biological or chemical monitoring of the effects of remediation activities should be implemented. For all practical purposes, risk may remain upon completion of the remedial action (residual risk).

Long-Term Risks Associated with Alternatives: the Residual Risks. Unless all sources of contamination are removed or isolated, there will be residual risks at the site upon completion of the remedial action. The COEC residuals could either remain or be quickly degraded, depending on the COEC's physical and chemical properties. The level of residual risk will depend on the effectiveness of the remedy in containing, treating, or removing site contaminants, and the quantity, and physical, chemical, and toxicological characteristics of residues or byproducts remaining at the site. Site COECs which remain onsite after the remedial action should be assessed for their potential risks.

This evaluation step focuses on a risk reduction assessment to determine if a potential remedial alternative is able to meet the remedial action goals and an assessment of residual risk potential. The findings of these tasks are compared among the alternatives to determine an array of preferred remedies based on the effectiveness of the remedies to satisfy remedial action goals with the least long-term health and environmental impact.

Remedial Action/Residual Risks vs. Baseline Risk. There are notable differences between remedial action/ residual risks and the baseline risk. The key difference is that baseline ecological risk refers to the potential risk to the receptors of concern under the "no remedial action" alternative. and remedial action and residual risks refer to short-term risks during remedial action and long-term risks which may remain after completion of the remedial action, respectively. Residual risk may be considered comparable to baseline ecological risk after remediation since in both cases the risks are chronic or subchronic in nature. Remedial action risks are generally short-term (acute or subchronic) risks.[8]

9.2.4 Nonrisk issues or Criteria as Determining Factors for Actions

The NCP recognizes that it is not possible to achieve zero risk in environmental cleanup: therefore, the approach taken by Superfund is to accept nonzero risk and return the site to its beat current use (not to conditions of a pre-industrialization era). Under RCRA, the preamble to the proposed Subpart S recognizes that cleanup beyond the current industrial land use should be justified. This section presents and discusses the nonrisk factors and recommends a balanced approach for resolution of issues to enable quality risk management decision-making. These factors can be categorized into scientific and nonscientific factors, as explained below.

9.2.4.1 Scientific Factors

The scientific factors, including engineering design and feasibility, should be considered in risk management decision-making. These factors focus on technology transfer (realistic performance of the technology), duration of protection, and feasibility study data uncertainties. These factors will influence the decision whether or not to proceed with selection of a particular remedy. They are

Technology Transfer. This factor concerns the treatability of the contaminated debris or media by a preferred technology or early action. Although the recommended technology may appear attractive, a number of problema must be overcome before actual selection or implementation of the action. The following are a few examples:

- Scale up.
- Downtime and maintenance (including supplies).
- Ownership/control.
- Throughput to meet the required completion schedule.
- Skills required or training requirements.
- Quantitation and detection limits.
- Space requirements for the remediation process and management of remediation wastes.

Duration of Protection. This factor concerns the duration of the removal or remedial technology designed to treat or address site risk. This factor is particularly important for site radionuclides or NAPL compounds in the aquifer. The maintenance or replacement of barriers or equipment is also a primary concern for this factor. Although a technology or alternative is effective, its effectiveness may not last long if there is no source control or if contamination from offsite sources is not controlled.

Data Uncertainty. This factor considers reliability and uncertainty of certain site or feasibility study data for use in selecting a remedy, or for determining whether no further action is appropriate. Uncertainty in the following data may also impact the risk analyses or baseline risk assessment results:

- Adequacy of bench-scale or pilot-scale treatability data.

[8] One exception (i.e., remedial action risk which is long-term) is a pump-and-treat remedy of groundwater to meet MCLs for organics which pose a threat to human health but not ecological receptors. If the effluent is discharged to a surface water body and happens to contain trace elements at high levels (or other COECs not reduced by the treatment process), then an exposure route to environment receptors may remain which is not addressed by the baseline ERA, and which will exist for the operational life span of the remedy.

- Data uncertainties (volume, matrices, site geology/hydrogeology).
- Field data and modeling data.
- Overall uncertainty of the source of site contamination.

9.2.4.2 Nonscientific Factors

Nonscientific factors should also be considered in risk management decision-making because some of these factors are key to a successful site remediation. Most of these factors are internal, but can also be external. Examples of these factors are enforcement, compliance, schedule, budget, competing risk reduction priorities, community inputs, and societal/economic value of the resources to be protected. These factors will influence the decision on whether or not certain removal or remedial actions should be taken, or on which remedies are to be selected These factors are detailed below.

Enforcement and Compliance. Certain courses of action (including risk management decisions) have been agreed upon early in the process and have been incorporated in the IAG or FFA. This is particularly germane to some earlier HTRW sites.[9] Nonetheless, the requirements specified in the enforcement documents or administrative order of consent, IAG, or FFA should be followed by the risk manager or PM with few exceptions. When risk-related factors or other nonrisk factors are over-arching, the risk manager should then raise this issue to higher echelon or to the legal department for further action or negotiation.

Competing Risk Reduction Priorities. Although related to risk, this factor represents the competing interest among programs or within the project for a limited source of funding to perform risk reduction activities. Since it is likely that not all sites will be cleaned up at an equal pace, the planning and execution of environmental restoration among these units should follow a prioritization scheme. However, the scheme developed according to risk may not be the same according to the customer, the base commander, or the agencies. The risk manager or PM must seek common ground to resolve this issue so that resources can be expended to produce incremental environmental benefits.

Schedule and Budget. These factors usually go together because the more protracted the project life, the more resources the project will demand. While each PM would like to comply with risk-based considerations with little margin of error, the PM may have no choice but to make risk management decisions with larger uncertainties than he or she would prefer, due to schedule and budget constraints.

Community Input. Opportunity for the stakeholders or community to provide input into the permit modification is provided when primary documents are prepared, i.e.. RFI Work Plan, RFI/CMS reports, the proposed remedies, and the CMI Work Plan. Superfund also provides similar opportunities for public participation. To be successful in site remediation and closeout, the risk managers must be able to communicate risks effectively in plain and clear language without bias. Early planning and solicitation of community input is essential to democratization of risk management decision-making. Some of the following issues may be of concern to the communities:

- Ineffective communication of risks and uncertainties.
- Lack of action (some action is preferred to no action).
- Not in my backyard (offsite transportation of contaminated soil, debris, or sediment should avoid residential neighborhoods).
- Any treatment effluent or discharge is unacceptable (onsite incineration is seldom a preferred option except for mobile incinerators, in certain instances).
- The remedy should not impede economic growth or diminish current economic and recreational value of resources to be protected.
- Cleanup will improve the quality of life and increase property values or restoration of recreational/ economic resources.

Societal/Economic Value of the Resources to be Protected. This nonrisk factor concerns the community sentiment on how fast or in what manner the resources

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[9] USACE has published the *Technical Project Planning -- Guidance for HTRW Data Quality Design* (USACE 1995b) which purpose is to build flexibility for site decision-making based on data need, use, and project objective and strategy. This new way of project planning and execution will be likely to result in a more effective risk management decision-making for the new HTRW sites.

impacted by site contaminants should be restored. These resourcea may include surface water bodies, wildlife, and game animals. Most communities would like to see impacted resources restored to original use: however, this can be difficult to achieve. Some communities may be willing to accept natural attenuation or no action options for impacted surface water bodies, given the opportunity to examine the pros and cons of all options. Therefore, it is recommended that the risk manager execute a community relations plan in earnest in order to solicit the citizens' input on the risk reduction approach and issues of concern. Key community spokespersons may also be appointed to the site action committee to facilitate such dialogue and communication.

9.2.4.3 A Balanced Approach

In conclusion, the risk manager should consider all risk and nonrisk criteria before making risk management site decisions. Due to uncertainties associated with ERA or analysis, the decision-maker must review risk findings and the underlying uncertainties, and consider other nonrisk factors in the overall risk management equation. When making risk management decisions, the risk manager should keep an open mind regarding the approaches to meet the project objective. In order to make informed site decisions, the risk assessor must present risk estimates in an unbiased manner. With an understanding of the volume of contaminants of concern, significance and biological relevance of the ecological effects and potentially impacted receptors, fate/transport properties of the COECs, and completeness of the exposure pathways and the food web, the risk manager, PM, and stakeholders will be better equipped to make informed decisions. These decisions should be consistent with the overall site strategy, which is developed early in the project planning phase (see Chapter 2). and which may evolve throughout the project.

9.3 Design Considerations

Risk assessment methodology can be an important tool in the design phase of CERCLA remedial actions or RCRA corrective measure implementation. During the early phase of RD/RA or CMI, risk assessment results can help determine: 1) whether the selected remedy can be implemented without posing an unacceptable short-term risk or residual risk and 2) control measures (operational or engineering) to mitigate site risks and to ensure compliance with ARARs, and to-be-considered requirements, and permit conditions. The risk and safety hazard information will be evaluated by the site decision-makers, along with information concerning design criteria, performance goals, monitoring/compliance requirements, prior to making risk management decisions regarding the above questions. Further, the decision-makers consider potential requirements such as ARARs and to-be-considers TBCs) in determining design changes of control measures.

This section addresses the above issues. i.e., risk management considerations in remedial design, compliance with ARARs, including the CAA, CWA, ESA, and other major environmental statutes, and control measures required to mitigate risks.

9.3.1 Potential Risk Mitigation Measures

Engineering Control - Where appropriate (when short-term risks are determined to be unacceptable), engineering controls should be recommended by the design engineer with inputs from the risk assessor, aquatic ecologist, compliance specialist, and the air modeler. Examples of these control measures include:

- VOC and SVOC emissions - activated carbon canisters, afterburners, or flaring, prior to venting.
- Metals and SVOC airborne particles - wetting of work areas; particulate filter/bag house, wet scrubber, or electrostatic precipitator (for thermal treatment devices or incinerators).
- Fugitive emissions - monitoring of valves, pipe joints, and vessel openings: and barrier/enclosure of work areas (e.g., a can or shield over the augering stem).
- Neutralization or chemical deactivation of effluent (continuous process or batch).
- Use of remote-control vehicle for handling, opening, or cutting of drums containing explosive or highly reactive or toxic substances.

9.3.1.1 Operational Control

Where appropriate, administrative control measures (procedural and operational) safeguards should be recommended by the PM, design engineer, and field supervisor during RA, with inputs from the risk assessor and other relevant technical and compliance specialists. Examples of these control measures include:

- Establish short-term trigger levels which will require work stoppage or upgrade of the remediation procedures (e.g.. dredging of toxic sediments). Either biological or chemical indicators, or their combination could be used as the bigger levels. These levels should be developed in the RD/RA or CMI project phase by the risk assessor and other technical specialists, including the modeler.

- Consistent with the above trigger or acute concern levels. evaluate onsite performance with field equipment to ensure adequate remediation.

- Afford the proper protection of sensitive environments by careful planning and positioning of staging area. storage or management of remediation wastes, selection of equipment with low load bearing, and season or time period when the remediation should be completed.

- Establish a zone of decontamination and proper management of effluent or waste generated from this zone.

- Secure and control access to areas where remedial actions are being implemented at all times.

9.3.1.2 Institutional Control

Although institutional control may not be relevant for ecological receptors, it can be relevant in the sense that institutional control measures may be needed to reduce human intrusion, thus allowing the sensitive environments to recover or the ecological receptors to re-establish. Institutional controls are particularly pertinent for remedies which involve containment, onsite disposal of wastes, or wetlands remediation. Institutional controls should be recommended by the customer, PM, and other site decision-makers. Examples of these control measures include:

- Recording land use restrictions in the deeds (deed restrictions) for future use of certain parcels or areas where hazardous substances or wastes are contained.

- Erection of placards, labels, and markers which communicate areas where human exposure may pose short-term or residual risks.

- Security fences and barriers.

9.3.2 Risk Management; Degree of Protectiveness

Not only should a selected remedial action (corrective measure) be able to meet balancing criteria, the remedial action must be protective, i.e., in terms of reducing site risks. In designing a selected remedy, the site decision-makers may face operational or engineering issues which are likely to require risk management decisions. For example, if a detailed analysis of a selected remedy reveals potential short-term or residual risks, the decision-makers must decide to what extent and with what control measures are necessary to abate the risk. Inputs from the risk assessor will be needed to help make informed risk management decisions. The following are examples of key risk management considerations for designing an effective remediation strategy:

- **Acceptability of control measures.** There are potential operational (procedural) or engineering control measures to address the short-term risks. The risk assessor, in coordination with the design engineer, expert ecologist(s)/advisory panel, and other project team members, assesses the effectiveness of any proposed control measures.

- **Removal of control measures.** Before a control measure is implemented; the decision on the minimum performance and when to stop requiring the control measure has to be addressed. This is particularly important if control measures are costly to implement and maintain.

- **Effectiveness of the remediation.** Remediation should effectively address onsite contamination if there is a continuing offsite (regional) source. This consideration is particularly important for groundwater and sediment contamination remediation. This regional source control strategy should not be confused with the identification of PRPs since some of the discharges could be a permitted activity. Nonetheless, this issue has to be resolved if the RAOs are risk-based and do not consider offsite influences or contribution to the contaminants requiring remediation. Offsite source control and containment. waste minimization, and closure issues should be raised by the risk manager to the agencies, USACE customers, and higher echelon.

- **BRAC.** With BRAC, the land use. of closed defense facilities may not be indefinitely controlled and the legislation governing BRAC holds the U.S. government responsible for future cleanup of contamination caused by government activities. Cleanup criteria and long-term remedies should take land use into consideration for implementation of an effective site closeout strategy (see. Chapter 2). For example, conversion of military bases into a state park or refuge area will require different cleanup objectives than cleanup to the level acceptable for industrial/commercial usage. This issue should be addressed early in the site strategy development phase with input from customers, local redevelopment commissions, state, and other stakeholders.

- **Verification of cleanup.** The risk management decision concerning verification of cleanup, i.e., the numerical value of the RAO, should be based on a combination of factors: risk, uncertainty, statistics, analytical detection limits/ matrices, and costs. Although RAOs have been negotiated or determined in the ROD, the sampling method and statistical requirements must be clearly articulated before design and implementation of the corrective measures or remedial alternatives.

Risk management decisions during the design phase of a CERCLA or RCRA remediation should be flexible, considering the uncertainty in the risk assessment results, acceptable risk range, confidence level of toxicity data or criteria to support the assessment, engineering feasibility, reliability of the measures (operational changes versus pollution control equipment), state and community acceptance, and cost. It is recommended that risk managers and site decision-makers request input from all members of the project team for pros and cons of proposed control measures to address the short-term risks.